UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-op-45090

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 17-op-45004

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

WALGREENS' REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Even if Plaintiffs could prove Walgreens violated the Controlled Substances Act ("CSA") by shipping suspicious orders of prescription opioids to the Track One counties without adequate due diligence (they cannot, *see* Dkt. 2149), and even if Plaintiffs' claims against Walgreens were not completely barred by the statutes of limitations (they are, *see* Dkt. 1872/1874¹), Plaintiffs *still* cannot point to any evidence that pills Walgreens shipped to its stores in Cuyahoga or Summit Counties were *actually diverted* out of legitimate medical channels. In response to Walgreens' motion, Plaintiffs effectively concede as much. Without evidence of diversion, Plaintiffs cannot connect any allegedly wrongful conduct by Walgreens to any alleged harm.

In response, Plaintiffs suggest that it may be enough merely to allege technical violations of the CSA and a high volume of shipments. It is *not* enough. As Walgreens has explained, "the DEA has flatly dismissed the idea that volume alone indicates (let alone proves) actual diversion" and "Plaintiffs' own law enforcement officials agree." Dkt. 1871/1876 ("Br.") at 4. It is clear that Plaintiffs must show actual diversion to prove causation. They cannot.

Indeed, Plaintiffs have not pointed to *any* evidence of *any* diversion from *any* Walgreens store in either of the Track One counties. Plaintiffs do not dispute that there is no evidence in this case that any Walgreens pharmacy in Cuyahoga or Summit County filled even one invalid prescription.

Because there is no evidence of diversion, Plaintiffs cannot prove that Walgreens caused any of their claimed injuries. Therefore, all of Plaintiffs' claims fail as a matter of law, and the Court should enter judgment in favor of Walgreens.

¹ On first reference, citations to briefs and deposition transcripts filed on the docket include docket numbers (sealed and public, if both are available). Unless otherwise indicated, all *emphases* in this brief have been added.

I. PLAINTIFFS MUST PROVE ACTUAL DIVERSION²

Unstated but implicit throughout Plaintiffs' response is the remarkable theory that, even if every single order Walgreens distributed to its pharmacies in the Track One counties went to fill legitimate prescriptions written by licensed physicians for patients with legitimate medical needs, Walgreens should *still* be liable because it had a lot of stores and served a lot of patients—thus contributing to the overall volume of prescription opioids in the Track One counties, which Plaintiffs' experts opine are tied to negative outcomes. *See* Dkt. 2190/2205 ("Opp.") at 2. But even if it is true that higher total prescription volumes are associated with negative outcomes on a community-wide basis, that is *not* a theory under which *Walgreens* can be liable. Walgreens does not write prescriptions, and Plaintiffs have never alleged that Walgreens—as opposed to certain other Defendants—misled prescribers or caused them to overprescribe opioids in the Track One counties (or anywhere else, for that matter).

Plaintiffs' claims against Walgreens require proof of actual diversion. Br. at 2-3. Walgreens has been sued as a distributor, for shipping "suspicious" orders without adequate due diligence (*i.e.*, "improper distribution"). From the outset of the litigation, Plaintiffs have *always* claimed that the foreseeable and actual harm that makes improper distribution tortious is *diversion*. Thus, any causation theory that fails to include actual diversion from "suspicious" orders shipped by Walgreens fails as a matter of law, eliminating the critical connection between

² Walgreens incorporates by reference Defendants' additional causation briefing, *see* Dkts. 1869/1885 and 1897/1920, as well as the simultaneously filed replies by the Pharmacy and Distributor Defendants.

³ See, e.g., Dkt. 513, SAC ¶ 929 ("[Defendants' violations] allowed the widespread *diversion* of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic."); Opp. at 18 (arguing that "*diversion* is foreseeable if registrants fail to comply with federal law" by "shipping a suspicious order without due diligence"). In denying Defendants' motions to dismiss, this Court recognized that this is Plaintiffs' theory. See, e.g., Dkt. 1203, Opinion & Order at 9-10 (permitting RICO claims to proceed against certain Distributor Defendants based on Plaintiffs' pleading of a "direct chain of causation," including that "the excess opioids . . . distributed . . . were then *diverted* into an illicit, black market"); *id.* at 38 ("According to Plaintiffs, Defendants' conduct allowed the *diversion* of opioids and thereby created a black market for their drugs.").

Walgreens' purported misconduct and Plaintiffs' claimed injury. 70 Ohio Jur. 3d § 36 (2019) ("In order to recover in an action for a negligent injury, *the negligence complained of* must be the direct and proximate cause of the injuries inflicted. . . . [T]he mere coexistence of negligence and injury is not sufficient to establish a causal connection between the two."). Indeed, Plaintiffs have no standing to bring this suit if they cannot demonstrate "a causal connection between the injury *and the conduct complained of*." *Bennett v. Spear*, 520 U.S. 154, 167 (1997).

Plaintiffs sued Walgreens for allegedly turning a blind eye to diversion that caused them harm. At summary judgment, they must adduce evidence that diversion in fact occurred.

II. PLAINTIFFS CANNOT PROVE ACTUAL DIVERSION

Plaintiffs cannot show actual diversion because all they have is volume and volume is not enough. See Br. at 2-4. DEA and Plaintiffs' own law enforcement officials agree. See id. at 3-4. There is simply *no evidence* from which *any* reasonable juror could conclude that a Walgreens store in either of the Track One counties ever dispensed prescription opioid medications except to fill valid prescriptions written by licensed medical professionals for patients with legitimate medical needs. Indeed, Plaintiffs concede as much: "Plaintiffs do not intend to assert, either in expert opinions or factual presentations at trial, that any specific prescription was unauthorized, medically unnecessary, ineffective, or harmful, or that the filling of any specific prescription caused or led to harm for which Plaintiffs seek to recover." Dkt. 1058 at 3 (Plaintiffs' Response to Discovery Ruling No. 5). In other contexts, Plaintiffs have also admitted, as they must, that they "do not allege violations of statutes or regulations applicable specifically to retailers who sell opioids" by Walgreens or any of the other Pharmacy Defendants. Dkt. 654 at 75 n.47 (Opposition to Defendants' Motions to Dismiss). Plaintiffs do not dispute that there is zero evidence that any of Walgreens' stores in the Track One counties operated like "pill mills" that dispense controlled substances without valid prescriptions. See Br. at 5.

Perhaps recognizing the futility of the endeavor, Plaintiffs spend almost half of their brief repeating arguments from their motion for summary judgment focused on Defendants' alleged failure to comply with the CSA. *See* Opp. at 2-9; *compare* Dkt. 1924/1910 at 105-122 (reciting virtually identical allegations). Walgreens has already responded to those arguments in detail, making clear why they are both wrong and misleading. *See* Dkt. 2149 at 63-77. In any event, those arguments are completely irrelevant to the only question in *this* motion: whether any prescription opioids Walgreens shipped into the Track One counties were actually diverted.

Plaintiffs' meager (and half-hearted) efforts to engage with Walgreens' actual motion and the handful of new arguments they do offer are equally irrelevant.

A. Plaintiffs' Expert Witnesses Do Not Identify Actual Diversion

In its opening brief, Walgreens explained that none of Plaintiffs' experts identify "any evidence connecting any allegedly 'suspicious order' shipped by Walgreens into Cuyahoga or Summit Counties to any actual diversion." Br. at 5. That conclusion is unrebutted. Just like Plaintiffs themselves, Plaintiffs' experts point to volume and nothing else.

As to McCann, while Plaintiffs misleadingly describe his report as flagging "suspicious orders," they do not deny that McCann has in fact expressly *disavowed* any opinions about whether any of the orders he flagged are "suspicious" or led to diversion in the real world. *Id.* at 6. Plaintiffs likewise admit that all of the charts and analysis in McCann's report are aggregated, with no analysis at the individual store level where diversion would occur. *See* Opp. at 17. Instead, Plaintiffs are left to posit that it is somehow enough that McCann attached to his report a large spreadsheet purporting to list flags for individual orders shipped by Walgreens into the Track One counties. But a list of flagged transactions—even if any were truly "suspicious"—is

no more evidence of actual diversion than aggregated charts.⁴ Such a list still fails to provide any of the store-level context necessary to indicate potential diversion rather than legitimate medical demand. And even if it did, Plaintiffs' DEA expert, Rafalski—the expert presumably retained to tie McCann's data to some quantifiable risk of diversion—never even *reviewed* the spreadsheet in question, or *any* analysis by McCann other than his aggregated charts. Br. at 8.

As to Rafalski, Plaintiffs do not dispute that his report contains no opinions about actual diversion and concedes that determining whether controlled substances are "likely to be diverted into illicit channels" requires a highly individualized, store-level analysis that neither Rafalski nor any of Plaintiffs' other experts have conducted. *Id.* at 7-8. Plaintiffs do not even attempt to defend Rafalski's unfounded "opinion" that 95% of all orders Walgreens shipped into the Track One counties were actually diverted. *Id.* In fact, in response to Defendants' *Daubert* motion, Plaintiffs have disavowed that opinion altogether—along with any other "opinions" about the likelihood of diversion not contained in Rafalski's report. Dkt. 2253/2260 at 23, 25.

Instead, Plaintiffs argue that a more general conclusion—*i.e.*, that shipping suspicious orders *could* lead to diversion—is supported by the DEA Diversion Investigator's Manual.

See Opp. at 17-18. That Manual says only that orders exceeding a certain threshold "over *extended* periods of time" suggests that controlled substances "*possibly* are being diverted" and warrants investigation. DEA Diversion Investigator's Manual (1996) (quoted in Dkt. 2000-22/1999-21 at 15-16) ("Manual"). Of course, Rafalski nowhere opines that Walgreens' shipments ever triggered the Manual's criteria. Nor could he. None of McCann's analyses (on which Rafalski relies) reflect the Manual's stated threshold. *Id.* McCann did not conduct *any*

⁴ This is especially true when the vast majority of the transactions McCann "flags" in the spreadsheet are *not* based on any of the algorithms identified in McCann's report but instead on Plaintiffs' arbitrary instruction to flag *every* subsequent transaction once a single transaction is flagged. *See* Dkt. 1903-2/1906-2 at 4, 11-12.

analysis of flagged orders by individual stores. Rafalski, in turn, conducted no analysis of his own. Br. at 8. But even if Plaintiffs' experts *had* identified any Walgreens stores placing suspicious orders over extended periods of time, Plaintiffs still have no evidence that any "possibly" (not even probably) diverted orders were *actually* diverted.

Similarly irrelevant is Plaintiffs' reliance on testimony from the DEA's 30(b)(6) witness that diversion is "foreseeable" when registrants do not comply with the CSA. Opp. at 18. Of course, whether diversion is *foreseeable* if distributors violate the CSA is meaningless *if no diversion in fact occurred*. The foreseeability of hypothetical diversion is not evidence of actual diversion in any particular case. For exactly this reason, the same DEA 30(b)(6) witness testified that even a truly suspicious order does not necessarily indicate diversion, Br. at 3-4, and the Manual says that even suspicious orders placed "over extended periods of time" show only that controlled substances are "possibly" being diverted, *see* Manual.

Plaintiffs finally appeal to the more theoretical opinions of certain causation experts. *See* Opp. at 2, 18. At most these experts purport to identify a relationship between increased total volumes of prescription opioids shipped from all sources to a geographic region and negative outcomes related to abuse and mortality across the community. While such opinions may be relevant to Plaintiffs' theories against the Manufacturer Defendants, they do not support any theory against *Walgreens*. *See supra* at 2-3. As Plaintiffs' experts admit, it is "prescription activity[]"—*i.e.*, by doctors, not distributors or pharmacies—"which drives shipments to an area." Gruber Rpt., Dkt. 2000-6/1999-6 at 52. Like Plaintiffs, none of these experts points to any evidence or offers any opinion that Walgreens—as opposed to other Defendants alleged to have engaged in misleading marketing—influenced "prescription activity" in the Track One counties.

Neither do they point to evidence or offer opinions that any prescription opioids shipped by Walgreens to the Track One counties were actually diverted into illicit channels.

B. A DEA Action in Florida Does Not Show Diversion in Track One

Perhaps nothing reveals Plaintiffs' complete lack of causation evidence against

Walgreens *in Cuyahoga and Summit Counties* as clearly as their dogged reliance on allegations in a 2012 DEA action against Walgreens *in Florida*. See Opp. at 6-11. DEA's Florida allegations are incomplete, misleading, and, most importantly, irrelevant to distribution claims in *Ohio*. See Br. at 5; see also Dkt. 2149 at 64. But those allegations also stand in stark contrast to the complete absence of evidence adduced by Plaintiffs in *this* litigation. Plaintiffs are left with no choice but to argue that Walgreens' alleged misconduct in Florida caused harm to the Track One counties on the theory that some unspecified quantity of pills "migrated" to Ohio, Opp. at 10-11—because they can point to nothing else. But even if one accepts the notion that certain unidentified individuals traveled from Ohio to Florida at some unknown point in time to get pills of unspecified type or quantity, Plaintiffs still cannot identify a single such pill that actually ended up in the Track One counties, much less one that was distributed or dispensed by Walgreens or tied in any way to DEA's Florida allegations.

Additional flaws plague Plaintiffs' contention that if something happened in Florida, it must have happened in Ohio, too. *Id.* at 2, 9-10. For one, Plaintiffs simultaneously argue *against* that very theory in their briefing on Defendants' statute of limitations defenses. *See* Dkt. 2179/2212 at 9, 30 (arguing that DEA enforcement actions outside the limitations window did not put them on notice because they involved "distribution facilities *in other states*" and that an action based on a theory of "if it happened there, it must be happening here" would "likely have

been dismissed"). Plaintiffs cannot have it both ways.⁵ For another, quite unlike DEA in Florida, Plaintiffs have disavowed any allegations of improper *dispensing* by Walgreens pharmacies in Cuyahoga or Summit Counties. *See supra* at 3. So, even if evidence of allegedly improper *distribution* in Florida was relevant to distribution claims in Ohio (it is not), Plaintiffs are still without any evidence that any allegedly improper shipments of prescription opioids were actually diverted from a Walgreens pharmacy in the Track One counties.⁶

C. Walgreens' Efforts to Combat the Crisis Do Not Show Diversion

Plaintiffs try to suggest that a handful of Walgreens' own documents and deposition testimony by Walgreens employees create a triable issue on diversion because they refer to some connection between either (1) suspicious order monitoring and diversion in general or (2) the volume of opioid prescriptions in the United States and the nation's opioid epidemic. *See* Opp. at 11-12. In fact, not one of these documents or depositions says what Plaintiffs want it to say.

None of them even comes close to creating a disputed question for the jury about whether any of Walgreens' shipments to its stores in Cuyahoga or Summit Counties were in fact diverted.

For instance, the fact that Walgreens built a state-of-the-art SOM system in part to "manage the amount of controlled substance product that is shipped to [Walgreens] stores," *id.*Ex. 48, is in no way an admission that excess orders were shipped—much less diverted. The fact that one purpose for reporting suspicious orders to DEA is to help DEA identify diversion, *see*

⁵ Walgreens can. DEA's allegation in Florida plainly put Plaintiffs on notice that they had potential claims and triggered the applicable statutes of limitation, but those allegations—which never even *mention* Cuyahoga or Summit Counties—do not stand as evidence of any actual diversion in the Track One counties.

⁶ Plaintiffs misleadingly argue that an email and attachments sent from Anda to Walgreens in 2012 shows that "the regulatory issues and red flags which led to the Jupiter DC ISO extended throughout Walgreens's nationwide operations, including Ohio." Opp. at 9-10. Anda's email reports on the results of a preliminary assessment—part of a larger know-your-customer process—in which Anda identified certain Walgreens stores that needed to submit a "completed questionnaire" before Anda would approve them for service. *See id.* Ex. 39. Far from suggesting diversion, this assessment was intended to gather the additional information necessary to make a due diligence determination. *See id.* Plaintiffs point to no evidence that any Walgreens stores in *Track One* were required even to submit a questionnaire, much less that Anda had concerns about *diversion* from a Track One pharmacy.

Swords Tr. at 203, Dkt. 1971-8/1984-26, is hardly evidence that any medications contained in those suspicious orders were actually diverted, see Br. at 3-4. Likewise, the fact that Walgreens recognizes a connection between overdose death rates and the "increased availability of opioid prescriptions," Opp. Ex. 49; that Walgreens has launched a "multi-million dollar effort" to provide "safe medication disposal kiosks" in pharmacies across the country, id. Ex. 1; and that Walgreens pharmacists work daily to reduce the stigma of seeking treatment and obtaining the overdose antidote naloxone, id. Ex. 2, hardly supports Plaintiffs' efforts to portray Walgreens pharmacies as "pill mills." The most that this "evidence" shows is that doctors may be overprescribing opioids and that Walgreens has been working hard to address the problem in the communities in which its pharmacists live and work.

D. AmerisourceBergen's Conduct Does Not Show Diversion by Walgreens

Because Walgreens stopped distributing all controlled substances in 2014 (meaning that all of Plaintiffs' claims are barred as untimely, see Dkt. 1872/1874), Plaintiffs' final ploy is to suggest—for the very first time in this litigation—that Walgreens shares responsibility for the ongoing and allegedly improper distribution of its vendor AmerisourceBergen. See Opp. at 12-14. Putting aside that distribution by another Defendant is wholly irrelevant to Plaintiffs' distribution claims against Walgreens, that Plaintiffs have already conceded that they assert no retailer claims against Walgreens, and that Plaintiffs cannot sub silentio change their claims without amending their complaints, Plaintiffs' new theory suffers from the exact same flaws as the old one: Regardless which distributor shipped the orders, Plaintiffs still can point to no evidence that any of the prescription opioids in those orders were actually diverted from any Walgreens pharmacy in Cuyahoga or Summit Counties.

CONCLUSION

The Court should enter judgment in favor of Walgreens on all of Plaintiffs' claims.

Dated: August 16, 2019

Respectfully submitted,

/s/ Kaspar J. Stoffelmayr

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of August, 2019, a notice of the foregoing has been served via CM/ECF to all counsel of record.

/s/ Kaspar J. Stoffelmayr Kaspar J. Stoffelmayr

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